APR 2 8 2003

510(K) Summary
ChromoCheck™ Antithrombin

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K023991

Submitters Name & Address:	Precision BioLogic Incorporated 900 Windmill Road, Suite 100 Dartmouth, Nova Scotia B3B 1P7 Canada
Contact Name:	Stephen L. Duff – Director of New Business Development Phone: 902-468-6422 ext. 224 Fax: 902-468-6421 Email: sduff@precisionbiologic.com
Preparation Date:	November 29, 2002
Device Name & Classification:	ChromoCheck™ Antithrombin Common Name: Antithrombin chromogenic assay Classification Name: Antithrombin quantitation Regulatory Class II, 81 JBQ
Predicate Device:	Chromogenix AB/ Instrumentation Laboratory Taljegardsgatan 3 S-431 53 Molndal Sweden, SW
Device Description:	ChromoCheck™ Antithrombin is a chromogenic assay consisting of a synthetic substrate, Factor Xa, and a Tris Heparin Buffer
Device Intended Use:	ChromoCheck™ Antithrombin is intended for use as a chromogenic assay for the quantitative determination of antithrombin activity in citrated human plasma.

Comparison to Predicate Device:

Parameter	ChromoCheck™ Antithrombin	Coamatic Antithrombin
Intended Use	Antithrombin quantitation	Antithrombin quantitation
Analytes	Antithrombin	Antithrombin
Component Reagent Matrices	**Reagent 1**: Chromogenic substrate in a distilled water matrix **Reagent 2**: Factor Xa – Bovine Factor Xa in a Tris Heparin Buffer matrix **Reagent 3**: Tris Heparin Buffer	**Reagent 1**: Chromogenic substrate in a distilled water matrix **Reagent 2**: Factor Xa – Bovine Factor Xa in a Tris Heparin Buffer matrix **Reagent 3**: Tris Heparin Buffer
Format	Lyophilized	Lyophilized
Packaging	4 x Substrate (3.75 mg) 4 x Factor Xa (5 µg) 4 x 5 mL Tris Heparin Buffer (Reconstituted volume – **2.5** mL) 4 x Substrate (3.75 mg) 4 x Factor Xa (5 µg) 4 x 10 mL Tris Heparin Buffer (Reconstituted volume – **5.0** mL)	2 x Substrate S-2772 (26 mg) 6 x Factor Xa (90 nkat) 6 x Buffer with heparin (25 mL)

Comments on Substantial Equivalence:

It is the opinion of Precision BioLogic Inc. that **ChromoCheck™ Antithrombin** is substantially equivalent to **Coamatic Antithrombin** (K022195), manufactured by Chromogenix AB (originally Kabi Pharmacia, Inc.), and currently marketed in the United States by Instrumentation Laboratory. This opinion is based on the following:

- both devices are based on synthetic chromogenic substrates
- both devices contain Factor Xa from a bovine source
- Both devices contain lyophilized reagents
- Both devices consist of a substrate, which is reconstituted with distilled water, Factor Xa, which is reconstituted with Tris Heparin Buffer, and Tris Heparin Buffer
- Both devices are intended for use in the quantitative determination of antithrombin activity in citrated human plasma
- Both devices present results as a % activity of antithrombin

Correlation:

Two lot numbers of ChromoCheck™ Antithrombin were compared to Coamatic® Antithrombin in a correlation study using a mix of 50 normal and pathological patient samples. The following correlation was achieved:

Correlation parameter	ChromoCheck Antithrombin Lot 1	ChromoCheck Antithrombin Lot 2
Y-intercept	1.389	-2.095
Slope	0.988	1.036
R^2	0.992	0.989

Conclusion: ChromoCheck™ Antithrombin is substantially equivalent to Coamatic® Antithrombin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 8 2003

Mr. Stephen L. Duff
Director of New Business Development
Precision BioLogic Inc.
900 Windmill Road, Suite 100
Dartmouth, Nova Scotia
Canada B3B 1P7

Re: k023991
Trade/Device Name: ChromoCheck™ Antithrombin
Regulation Number: 21 CFR 864.7060
Regulation Name: Antithrombin III Assay
Regulatory Class: Class II
Product Code: JBQ
Dated: March 26, 2003
Received: March 28, 2003

Dear Mr. Duff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K023991

Device Name: ChromoCheck™ Antithrombin

Indications for Use:

ChromoCheck™ Antithrombin is intended for use as an *in vitro* chromogenic assay for the quantitative determination of antithrombin activity in citrated human plasma.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023991

Rx ✓